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| 10/057,112 | 01/25/2002 | Kurt Osther | 45579/56876 | 1887 |

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| EXAMINER | |
|---|---|
| MILLER, CHERYL L | |
| ART UNIT | PAPER NUMBER |
| 3738 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/057,112 | OSTHER ET AL. | |
| | Examiner | Art Unit | |
| | Cheryl Miller | 3738 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *29-32,40-42,52 and 58-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-32,40-42,52 and 58-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 12, 2007 has been entered.

### *Response to Arguments*

Applicant's arguments filed June 12, 2007 have been fully considered but they are not persuasive. The applicant has argued that Lee (US 6,306,169) discloses a membrane placed *within* a cavity and not *over* a cavity. The examiner opinion is that the applicant has solely claimed ***materials or a kit***, therefore separate components that only are intended to be placed a certain way in the body. Lee discloses all the claimed components (such as the membrane) which has the *capability* of being placed over a cavity in the body. The applicant has also argued that Lee's suspension does not fill a cartilage free cavity, but instead fills the membrane. Again, it is the examiners position that the applicant has solely claimed ***materials or a kit***, therefore separate components that only are intended to be placed a certain way in the body. Lee discloses all the claimed components (membrane and suspension; separate components before implantation) which have the *capability* of being implanted in the manner intended by the applicant.

The applicant has argued that Minuth's (US 6,187,053 B1) stimulation molecule is not on the surface of the membrane, but instead on the suspension. The examiner disagrees. Minuth

discloses both applying the composition to the cells OR mixing the composition with the cells and embedding the cells in the composition, prior to applying the combination to the membrane (col.1, lines 42-51; col.2, lines 19-23; col.3, lines 10-12, 19-21). In the second arrangement, the composition as it surrounds the cells, will be in contact with the surface of the membrane and thus the membrane also carries the composition. Further, Minuth also discloses application of a composition to the membrane at col.3, lines 9-14. The applicant has argued the cells of Minuth are not capable of filling the cavity. The examiner disagrees, the cells are clearly shown filling the cavity in fig.2.

The applicant has argued that Tissel (which contains fibronectin and fibrinogen) will not create a signal transduction. This in non-persuasive to the examiner, because applicant has listed specifically fibronectin and fibrinogen in claim 30 and in specification to be elements which are non-collageneous proteins that induce a signal transduction, and Vibe-Hansen has disclosed the exact elements fibronectin and fibrinogen and therefore, Vibe-Hansen has disclosed what the applicant has claimed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29-32, 40-42, 52, 58-59, and 62-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al. (US 6,306,169 cited previously). Referring to claims 29 and 52, Lee discloses materials, or a kit for the repair of cartilage (col.1, lines 10-12), comprising a cartilage membrane (first matrix; col.5, lines 3-11), *for* application over a cavity (Lee's membrane is *capable* of being placed over a cavity; in another light, although may be disclosed to fill an entire cavity, the top portion of the membrane/matrix covers the cavity), the membrane comprising a surface part having a composition with a stimulation molecule (fibronectin, vitronectin, RGD, proteoglycans, etc., the same molecules disclosed by the applicant, are applied to the surface of the membrane, see col.5, lines 16-28) that induces a signal transduction in chondroblasts/chondrocytes (col.5, lines 18-20), and a suspension (gelled second matrix with cells; col.7, lines 5-12, 44-50) *capable* of filling the cavity beneath the membrane (the cell suspension is a **separate component before implantation** and is *capable* of filling the cavity alone; all that is claimed is materials or a kit, such separate components before assembled, which Lee discloses all claimed components that have capability of being assembled in the applicants intended manner).

Referring to claims 31-32 and 62-64, Lee discloses the membrane (first matrix) to be biodegradable, porous, collagen I (col.12, lines 7; col.5, lines 3-12, 29-40).

Referring to claims 30, 40-42, 59, and 65-68, Lee discloses the stimulation molecule to be a protein, including fibronectin, or others, having an RGD motif (col.5, lines 18-25).

Referring to claim 58, Lee discloses the suspension to comprise a chondroblast/chondrocyte suspension (col.7, lines 5-12).

Referring to claim 69, Lee's suspension is *capable* of being positioned between the cavity and the membrane.

Claims 29-32, 40-42, 52, 58-59, 62, 63, and 65-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Minuth (US 6,187,053 B1, cited previously). Referring to claims 29 and 52, Minuth discloses materials, or a kit *for* the repair of cartilage (*capable* of repairing any defect in joint tissues, see fig.1; 2), comprising a cartilage membrane (8), for application over a cavity (defect 5), the membrane (8) comprising a surface part having a composition (composition may be considered coating 10, which is disclosed to be mixed with cell suspension and applied to membrane, col.1, lines 47-51; col.2, lines 20-23, thus will be in contact with the surface of the membrane; OR composition may be considered cement, col.3, lines 9-13) with a stimulation molecule (proteins, col.3, lines 25-32) that induces a signal transduction in chondroblasts/chondrocytes, and a suspension (cells 9 in medium or medium alone may be considered the suspension; col.3, lines 50-57) *capable* of filling the cavity beneath the membrane (fig.2).

Referring to claims 31-32 and 62-63, Minuth discloses the membrane (8) to be biodegradable, porous, collagen (col.1, lines 35-40; col.3, lines 7-8).

Referring to claims 30, 40-42, 59, and 65-68, Minuth discloses the stimulation molecule to be a protein, including fibronectin, or others, having an RGD motif (inherently present in fibronectin; col.3, lines 25-32).

Referring to claim 58, Minuth discloses the suspension to comprise a chondroblast/chondrocyte suspension (col.3, lines 15-16).

Referring to claim 69, Minuth's suspension (9) is placed between the cavity (5) and membrane (8; see fig.2).

Claims 52, 60 and 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz (US 2003/0036801 A1). Schwartz discloses a kit (components shown in fig.4) comprising a cartilage membrane (top 28), an interface membrane (bottom 28) each membrane having a composition with a stimulation molecule (membranes disclosed to also have bioactive agents such as fibronectin, stimulants, cells, etc; P0065, P0070), and a suspension (cells osteoblasts AND chondrocytes in suspension 26; P0043-P0049) *capable* of filling a cavity above and below the interface membrane.

Claims 52, 60 and 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Chu et al. (US 2005/0014252 A1). Chu discloses a kit (components shown in block embodiment in fig.1; P0101-P0105) comprising a cartilage membrane (top layer), an interface membrane (base layer) each membrane having a composition with a stimulation molecule (RGD's; P0147), and a suspension (cells osteoblasts AND chondrocytes in suspension P0143, P0149) *capable* of filling a cavity above and below the interface membrane.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29-32, 40-42, 52, 58-60, and 62-69 are rejected under 35 U.S.C. 102(e) as anticipated by Vibe-Hansen et al. (US 5,989,269, cited previously) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lee et al. (US 6,306,169, cited previously). Referring to claims 29 and 52, Vibe-Hansen discloses a materials and kit for cartilage repair (col.2, lines 35-40) comprising a cartilage membrane (covering patch 2) having at least one surface part carrying a composition (Tissel; Tissucol, or Adhesive Protein; col.5, lines 32-37) comprising at least one stimulation molecule (fibronectin; col.6, lines 55-55), which induces a signal transduction in chondroblasts/chondrocytes (fibronectin and fibrinogen, col.5 lines 7-10, are both in or attached to the patch 2, *and inherently induce a signal transduction in chondrocytes*; even though they are elements of the Tisseel adhesive, and applicant has argued that they will not create a signal transduction, this in non-persuasive, because applicant has listed specifically fibronectin and fibrinogen in claim 30 to be elements which are non-collageneous proteins that induce a signal transduction, and Vibe-Hansen has disclosed the exact elements and therefore, Vibe-Hansen has disclosed what the applicant has claimed), and a suspension (3) capable of filling a cavity. *In the alternative*, if not inherent that fibrinogen in the compositions of Vibe-Hansen would cause a signal transduction, it would have been obvious for the reasons below. Although Vibe-Hansen discloses a cartilage membrane for repairing a defect in cartilage, Vibe-Hansen does not disclose a surface composition with a signal tranducing molecule. Lee teaches in the same field of repairing cartilage defects, use of a coating composition (coating) with a signal transducing molecule (fibronectin, vitronectin, RGD, etc) on the surface of cartilage membrane (first matrix), in order to modify the surface properties of the membrane, causing influence on cell attachment

and differentiation (thus signal transduction; col.5, lines 3-25). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Lee's teaching of placing a signal transducing molecule coating on a cartilage membrane, with the cartilage membrane of Vibe-Hansen, in order to provide an implant having modified surface properties, such as increased cell attachment and differentiation.

Referring to dependent claims 31-32 and 62-64, Vibe-Hansen discloses a non-immunogenic, non-toxic, biodegradable, substantially porous membrane made of collagen I (col.3, lines 8-11; col.5, lines 29-31).

Referring to dependent claims 30, 40-42, 59, and 65-68, Vibe-Hansen discloses the stimulation molecule to comprise fibronectin (which inherently comprises RGD; col.5, lines 32-36; col.6, lines 45-55), and in the alternative, Lee discloses such stimulation molecules (col.5, lines 15-25).

Referring to claim 58, Vibe-Hansen discloses a chondroblast/chondrocyte suspension (3; col.4, lines 53-55).

Referring to claim 60, Vibe-Hansen discloses an interface membrane (1; hemostatic barrier) *for* application over a cavity (is capable of being placed over a cavity) having two surface parts (top and bottom) each having stimulating molecules (fibrinogen, in Tissel; see above; or coating of Lee in the alternative) for chrondrocytes and osteocytes respectively, and a suspension capable of filling a cavity (3; same suspension used before may be used again; or a portion of the first suspension may be used for the second suspension).

Referring to claim 69, Vibe-Hansen's suspension is placed between the cavity and membrane (see fig.3c).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER